

Fortacin 150 mg/ml + 50 mg/ml cutaneous spray, solution

Lidocaine/prilocaine



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fortacin is and what it is used for
2. What you need to know before you use Fortacin
3. How to use Fortacin
4. Possible side effects
5. How to store Fortacin
6. Contents of the pack and other information

1. What Fortacin is and what it is used for

Fortacin is a combination of two medicines (lidocaine and prilocaine).

Fortacin is indicated for the treatment of lifelong premature ejaculation in adult men. It works by decreasing the sensitivity of the head of the penis to increase time before ejaculation.

2. What you need to know before you use Fortacin

Do not use Fortacin

- if you or your sexual partner are allergic to lidocaine or prilocaine or any of the other ingredients of this medicine (listed in section 6);
- if you or your sexual partner have a history of allergy or sensitivity to other local anaesthetics with a similar structure (known as amide-type local anaesthetics).

Warnings and precautions

Talk to your doctor or pharmacist before using Fortacin

- if you, or your sexual partner, have been diagnosed with a genetic disease or other condition affecting your red blood cells (glucose-6-phosphate deficiency, anaemia or methaemoglobinemia);
- if you have a history of medicine sensitivities, especially if you are not certain which medicine causes sensitivity;
- if you suffer from severe liver problems.

When you use this medicine, particularly during priming of the container, aim the container away from the face to avoid accidental contact with ears, eyes, nose and mouth.

If some medicine accidentally gets into your eyes or your partner's eyes, rinse them immediately with cold water or saline solution and cover them gently until any effects, such as numbness, wear off. Be aware that normal protective mechanisms, such as blinking, or sensation of a foreign body in the eye, may not occur until the numbness has worn off.

Fortacin may also come into contact with other mucous membranes such as your, or your partner's, mouth, nose and throat, causing them to feel slightly numb for a short while. As this will reduce the ability to feel pain in these areas, extra care should be taken not to injure them until the numbness has worn off.

During sexual intercourse, a small amount of this medicine may be transferred e.g. to the vagina or the anus. Therefore, both partners may feel slight numbness for a short while and should take care not to injure themselves, particularly during sexual activity.

Fortacin should not come into contact with a damaged ear drum.

Children and adolescents

Do not give this medicine to children or adolescents under 18 years of age.

Other medicines and Fortacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important if you are taking the following medicines which may interact with Fortacin:

- other local anaesthetics
- heart medicines (anti-arrhythmic medicines)
- medicines for high blood pressure and to regulate your heart rhythm (so-called beta blockers)
- medicines reducing your stomach acid (cimetidine)

The risk of a disorder reducing the amount of oxygen in the blood (methaemoglobinemia) may be increased if you are already taking medicines known to cause the condition, such as those listed below:

- Benzocaine – a local anaesthetic used to treat pain and itching
- Chloroquine, pamaquine, primaquine, quinine – used to treat malaria
- Metoclopramide – used to treat feelings of sickness (nausea) and vomiting, including in patients with migraine
- Glyceryl trinitrate (GTN, nitroglycerin), isosorbide mononitrate, erythryl tetranitrate, pentaerythritol tetranitrate and other nitrate and nitrite medicines - used to treat angina (chest pain caused by the heart)
- Sodium nitroprusside, isosorbide dinitrate – used to treat high blood pressure and heart failure
- Nitrofurantoin – an antibiotic used to treat urinary and kidney infections
- Sulphonamides (also called sulpha medicines) e.g. sulfamethoxazole – an antibiotic used to treat urinary infections, and sulfasalazine – used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis
- Dapsone – used to treat skin conditions such as leprosy and dermatitis and also to prevent malaria and pneumonia in high-risk patients
- Phenobarbital, phenytoin – used to treat epilepsy
- Para-aminosalicylic acid (PAS) – used to treat tuberculosis

The risk of methaemoglobinemia can also be increased by the use of certain dyes (aniline dyes), or the pesticide naphthalene, so let your doctor know if you work with any dyes or chemical pesticides.

Any barrier contraceptives (e.g. male or female condom), which are made from polyurethane-based material cannot be guaranteed to protect against disease or pregnancy when you are also using Fortacin. Check the material that your contraceptive or your partner's contraceptive is made of. Ask your pharmacist if you are unsure.

If you use Fortacin with condoms, you may be more likely to be unable to develop or maintain an erection. You may also be more likely to have reduced feeling in and around the penis.

Pregnancy, breast-feeding and fertility

Fortacin is not approved for use by women. Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Fortacin is not recommended for use whilst your partner is pregnant unless you use a male condom, as listed above, to prevent exposure of the unborn child.

Breast-feeding

This medicine may be used while your partner is breast-feeding.

Fertility

Fortacin may reduce the possibility of pregnancy, but is not a reliable contraceptive. Therefore, patients hoping to achieve conception should either avoid using Fortacin, or, if this medicine is essential to achieve penetration, should wash the penis as thoroughly as possible five minutes after Fortacin has been applied, but prior to intercourse.

3. How to use Fortacin

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Fortacin is 3 sprays (3 sprays = 1 dose) on the head of the penis before sexual intercourse. A maximum of 3 doses can be used within 24 hours with at least 4 hours between doses.

Instructions for use

Before initial use, briefly shake the spray container and then prime the pump mechanism by spraying the valve three times into the air. Aim the container away from faces to avoid contact with eyes, nose, mouth and ears. Before each subsequent dose, briefly shake the spray container and then re-prime the pump by spraying 1 time into the air.

Retract any foreskin from the head of the penis. Holding the can upright (valve up), apply 1 dose (3 sprays) of Fortacin to the entire head of the penis, by covering one third with each spray. Wait 5 minutes then wipe off any excess spray prior to having sexual intercourse.

If you use more Fortacin than you should

As this medicine is applied to the surface of the head of the penis the risk of overdose is low. If you do apply too much, wipe it off.

Symptoms of using too much Fortacin are listed below. Contact your doctor or pharmacist if you experience any of these. They are very unlikely to happen if it is used as instructed:

- Feeling light-headed or dizzy
- Tingling of the skin around the mouth and numbness of the tongue
- Abnormal taste
- Blurred vision
- Ringing in the ears
- There is also a risk of a disorder reducing the amount of oxygen in the blood (methaemoglobinaemia). This is more likely when certain medicines have been taken at the same time. If this happens, the skin becomes bluish-grey due to a lack of oxygen.

In serious cases of overdose, symptoms may include fits, low blood pressure, slowed breathing, stopped breathing and altered heart beat. These effects may be life-threatening.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with Fortacin in male patients:

Common (may affect up to 1 in 10 people)

- Inability to develop or maintain an erection
- reduced feeling in and around the penis
- feeling of burning in and around the penis

Uncommon (may affect up to 1 in 100 people)

- headache
- local irritation of the throat (if inhaled)
- irritation of the skin
- redness on and around the penis
- failure to ejaculate during sexual intercourse
- abnormal orgasm
- tingling in and around the penis
- pain or discomfort in and around the penis
- itching in and around the penis
- a high temperature

The following side effects have been reported with Fortacin in female partners:

Common: (may affect up to 1 in 10 people)

- feeling of burning in and around the vagina
- reduced feeling in and around the vagina

Uncommon (may affect up to 1 in 100 people)

- headache
- local irritation of the throat (if inhaled)
- vaginal thrush (Candida) infection

- discomfort in the anus and rectum
- loss of feeling in the mouth
- difficulty or pain passing urine
- pain in the vagina
- discomfort or itching in the vulva and vagina

Reporting of side effects

If you or your sexual partner get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at the website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fortacin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the spray container label and the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. You must throw away the container 12 weeks after you first use it.

The metal container is pressurised. Do not puncture, break or burn it even when apparently empty.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fortacin contains

- The active substances are lidocaine 150 mg/ml and prilocaine 50 mg/ml. Each spray delivers 50 microlitres which contains 7.5 mg lidocaine and 2.5 mg prilocaine.
- The other ingredient is norflurane

What Fortacin looks like and contents of the pack

Fortacin is a colourless to light yellow cutaneous spray, solution in an aluminium spray container with metering valve.

Each pack contains 1 spray container with 6.5 ml or 5.0 ml of solution.

Marketing Authorisation Holder

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in 07/2016

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.